REMARKS

Claims 1 – 20 are pending in the present Application. Claim 20 has been withdrawn from consideration, no claims have been canceled, Claim 10 has been amended, and no claims have been added, leaving Claims 1-19 for consideration upon entry of the present Amendment.

Claim 10 has been amended to correct a typographical error wherein the term "Staphlococcus" has been amended to "Staphylococcus."

No new matter has been introduced by this amendment. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1 – 19 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 4,775,585 to Hagiwara, et al. ("Hagiwara") in view of U.S. Patent No. 5,939,153 to Valyi ("Valyi"), and further in view of U.S. Patent No. 5,064,599 to Ando, et al. ("Ando"). Applicants respectfully traverse this rejection.

The present invention is directed to a method of making a shaped article, comprising thermoforming an article comprising an exterior surface comprising an inorganic biocidal agent and a first thermoplastic resin to form the shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article.

Hagiwara is directed to a polymer article containing zeolite particles. (See Abstract). The polymer article is produced, for example, by admixing bactericidal metal ion-containing zeolite particles with an organic polymer prior to molding, or by mixing a molded organic polymer containing a zeolite with a metal ion salt to form a metal ion-containing zeolite *in situ*. The Examples disclose molding the zeolite-containing polymer into fibers and yarns by a process of melting, spinning, and drawing. (Col. 13, ll. 23-25). Example 1 discloses that each knitted fabric was washed 50 times and then subjected to an evaluation of an antibacterial effect. (Col. 13, ll. 28-33). Hagiwara fails to disclose thermoforming the molded article.

Ando is directed to conjugated fibers comprising a low-melting point component and a high-melting point component, wherein the low-melting component comprises zeolite particles. (See Abstract). Upon heating, the low-melting component spreads to increase the surface area

and cause more zeolite particles to be exposed, which yields higher antibacterial activity in a fiber article produced from the conjugated fibers. (Abstract; Col. 8, ll.31-33). Ando fails to disclose thermoforming the molded article.

Valyi is directed to lined beverage containers. Valyi discloses a process for forming a multilayered plastic article and multilayered plastic preform and container, wherein a polyepoxide or a liquid crystal polymer in the liquid form is applied to a substrate in a thickness which varies over the extent of the substrate to form a multilayered substrate, forming a tubular liner from said multilayered substrate, and coating the tubular liner with an outer layer. (Abstract). The polyepoxides, especially the epoxy-amine thermosetting resins, are favored because the polyepoxides do not have to be shielded from beverage contact in a beverage container. (Col. 3, ll. 9-20).

In making the rejection, the Examiner has stated that given the substantially identical composition disclosed in Hagiwara and the presently claimed composition, he has a reasonable basis to believe that the claimed "shaped article has improved biocidal activity compared to the unshaped article" is inherently possessed in Hagiwara. (Office Action dated February 16, 2006, page 3). The Examiner further has stated that Ando clearly indicates that upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed, which yields higher antibacterial activity. The Examiner has stated that Hagiwara fails to teach or suggest that the molded article is prepared by a thermoforming process. To remedy this deficiency, the Examiner relies on Valyi to teach that plastic containers are typically prepared by a thermoforming process. The Examiner has stated that it would have been obvious to one of ordinary skill in the art to recognize the value of thermoforming for making a container or bottle.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5

U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. The present invention is directed to a shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article. Thermoforming comprises simultaneously heating and forming the article or multi-layer article, e.g., an extruded sheet, into the desired shape such as in a mold. Applicants have discovered that, unexpectedly, an article that is thermoformed to form a shaped article has superior biocidal activity over an article that is not thermoformed. As shown in Example 1 and Table 1 of the present application, thermoforming a biocidal article improves the silver release and thus the biocidal activity of the article. (¶ [0115]). The middle and side of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about 300% greater than the article that was not thermoformed, which had a silver release of 7.4 ppb.

Both Hagiwara and Ando are directed to fibrous articles. The Examiner relies on Ando for allegedly teaching that heating improves the exposure of zeolite on an article surface. Ando, however, does not provide as general of a teaching as the Examiner would suggest. Ando teaches that for the compositions disclosed therein with a low-melting point component and a high-melting point component, upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed. The teaching of Ando is thus limited to compositions that contain a low-melting component and a high-melting component. Thus, Ando does not provide the motivation to heat the compositions disclosed in Hagiwara, or an expectation of success for heating the compositions.

In order to find a reference for thermoforming, the Examiner combines the brief reference in Hagiwara to a container with a portion of Valyi, which is directed to a gas barrier liner for the inside wall of a beverage container. Applicants submit that one of ordinary skill in the art would not be motivated to combine references primarily directed to biocidal fibrous articles with a reference directed to a beverage container, and that there is no expectation of success for the use of the thermosetting technique of Valyi in the compositions of Hagiwara. Applicants also submit that Valyi expressly discloses that the useful materials for the liner to are only polyepoxides, preferably epoxy-amine thermosetting resins. (Valyi, Col. 3, ll. 9-20). In contrast, Hagiwara

fails to disclose polyepoxides. One of ordinary skill in the art would not be motivated to modify a reference that teaches a variety of thermoplastic polymers with thermoforming technique that is taught to be useful for a polymer that is not taught therein. In addition, one of ordinary skill in the art would be aware of the limitations of shaping a thermosetting polymer by thermoforming since a thermosetting polymer, such as the polyepoxides of Valyi, would not be as flowable as thermoplastic polymers.

Applicants further submit that Valyi teaches that both thermoforming and blow-molding yield similar results and either process can be used to shape an article depending on whether the original form is a sheet for thermoforming or a tube for blow-molding. (Col. 4, ll. 6-8). Therefore, upon reading Valyi, one of ordinary skill in the art would not be motivated to select thermoforming as compared to other methods of shaping an article. While one might try thermoforming and article such as that isclosed in Hagawara, this is not the standard for patentability. A finding of "obvious to try" does not provide the proper showing for an obviousness determination. The requirement for a determination of obviousness is that "both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (emphasis added). *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). An Examiner, then, cannot base a determination of obviousness on what the skilled person in the art might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do.

Finally Valyi fails to teach or suggest that its liner has biocidal activity or that thermoforming improves the biocidal activity of its liner.

In order to make the combination proposed by the Examiner, one would first have to combine Hagiwara and Ando, ignore the specific teaching in Ando directed to combinations of low-melting and high-melting polymer, and generalize their teaching of heating of zeolite-containing polymers. Ando does not even teach thermoforming. Then, in order to find a heating technique, one would have to focus on Hagiwara's passing reference to a container, ignore the list of useful polymers in Hagiwara, look to Valyi, which discloses containers made from completely different polymers, and apply the teachings to the polymers of Hagiwara. There is no teaching in Valyi that thermoforming should be applied to the polymers of Hagiwara, let alone polymers containing zeolites. One of skill in the art would not be motivated to make the

combination suggested by the Examiner, and there certainly would be no expectation of success for the combination.

For at least these reasons, the combined prior art teachings fail to provide a reasonable expectation of success by combining the references in the manner suggested by the Examiner. At best, this is only an "obvious to try" standard, which is not the proper standard for determining obviousness. Reconsideration and withdrawal of this rejection are respectfully requested.

Even where a *prima facie* case of obviousness exists, obviousness may be rebutted by a showing of "unexpected results," i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (emphasis added). The results must be of both statistical and practical significance. *Ex parte C*, 27 U.S.P.Q.2d 1492, 1497 (Bd. Pat. App. & Int. 1993).

As shown in Example 1 and Table 1, thermoforming results in a shaped biocidal article with about a 300% improvement in biocidal metal (e.g., silver) ion release over a biocidal article which is not thermoformed. The thermoformed article provides improved biocidal metal ion release and therefore improved biocidal activity. Applicants respectfully submit that the unexpected results disclosed in Example 1 would successfully rebut a *prima facie* case of obviousness, if it existed. Reconsideration and withdrawal of this rejection are respectfully requested.

It is further respectfully submitted that the Examiner has inappropriately used the doctrine of inherency in putting forth a rejection under 35 U.S.C. §103 (a). The Examiner has stated that " 'the claimed shaped article has improved biocidal activity compared to the unshaped article' is inherently possessed in Hagiwara." (Office Action dated February 16, 2006 page 3). Applicants respectfully submit that the prior art articles were not thermoformed and therefore would not be expected to have the properties that Examiner alleges are inherent. As described in Example 1 and Table 1 of the present application, a thermoformed article had silver release properties that were about 300% greater than an article that was not thermoformed. (¶ [0115]). An article that was not thermoformed therefore demonstrably does not inherently possess the biocidal metal release properties of a thermoformed article. In addition, the Examiner appears to state that if the prior art were modified to read upon the presently claimed invention, the prior art so-modified

would inherently possess the claimed properties of the present invention. This is an improper application of inherency.

The courts have repeatedly made the distinction that "the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Sporrmann*, 150 U.S.P.Q. 449, 452, (CCPA, 1966), citing *In re Adams*, 53 CCPA 996, 356 F.2d 998, 148 U.S.P.Q. 742. "Further it confuses anticipation by inherency, i.e., lack of novelty, with obviousness, which though anticipation is the epitome of obviousness, are separate and distinct concepts." *Jones et al. v. Hardy*, 220 U.S.P.Q. 1021, 1025 (CCPA, 1984) citing *In re Pearson*, 494 F.2d 1399, 181 U.S.P.Q. 641 (CCPA, 1974); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323 (CCPA, 1981). "The examiner should be aware that inherency and obviousness are distinct concepts." *Ex parte GPAC Inc.*, 29 U.S.P.Q.2d 1401, 1415, n. 15, *citing In re Naylor*, 369 F.2d 765, 152 U.S.P.Q. 106 (CCPA 1966); *In re Henderson*, 348 F.2d 550, 146 U.S.P.Q. 372 (CCPA 1965). "The theory of inherency is normally reserved for rejections under 35 U.S.C. § 102." *In re Grasseli*, 318 U.S.P.Q. 303 (Fed. Cir. 1983). Withdrawal of the rejection of obviousness under inherency is respectfully requested.

Reconsideration and withdrawal of this rejection are respectfully requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the rejection and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

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